ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA–R06–OAR–2013–0763; FRL–9927–01-Region 6]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants; Texas, Oklahoma, Arkansas, New Mexico, and the City of Albuquerque, New Mexico; Control of Emissions From Existing Sewage Sludge Incinerator Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve Clean Air Act (CAA) section 111(d)/129 negative declarations for the States of Texas, Oklahoma, Arkansas, New Mexico, and the City of Albuquerque, New Mexico, for existing sewage sludge incinerator (SSI) units. These negative declarations certify that existing SSI units subject to the requirements of sections 111(d) and 129 of the CAA do not exist within the jurisdictions of Texas, Oklahoma, Arkansas, and New Mexico (including the City of Albuquerque).

DATES: Written comments must be received on or before June 1, 2015.

ADDRESSES: Comments may be mailed to Mr. Guy Donaldson, Chief, Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth Boyce, (214) 665–7259, *boyce.kenneth@epa.gov.*

SUPPLEMENTARY INFORMATION: In the final rules section of this **Federal Register**, EPA is approving the negative declarations submitted by the Texas Commission on Environmental Quality (TCEQ), the Oklahoma Department of Environmental Quality (ODEQ), the Arkansas Department of Environmental Quality (ADEQ), New Mexico Environment Department (NMED) and the City of Albuquerque, New Mexico, certifying that there are no existing sewage sludge incinerator (SSI) units within their respective jurisdictions. These negative declarations meet the requirements of 40 CFR 62.06. EPA is approving the negative declaration as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action, no further activity is contemplated. If EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives relevant adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

For additional information, see the direct final rule, which is located in the rules section of this **Federal Register**.

Dated: April 16, 2015.

Ron Curry,

Regional Administrator, Region 6.

[FR Doc. 2015–10041 Filed 4–29–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 100

National Vaccine Injury Compensation Program: Statement of Reasons for Not Conducting Rulemaking Proceedings

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Denial of petition for rulemaking.

SUMMARY: In accordance with section 2114(c)(2)(B) of the Public Health Service Act, 42 U.S.C. 300aa–14(c)(2)(B), notice is hereby given concerning the reasons for not conducting rulemaking proceedings to add diabetes mellitus as an injury associated with the measles-mumps-rubella vaccine to the Vaccine Injury Table.

DATES: Written comments are not being solicited.

FOR FURTHER INFORMATION CONTACT: Avril M. Houston, MD, MPH, Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, Parklawn Building, Room 11C–06, 5600 Fishers Lane, Rockville, Maryland 20857, or by telephone at (301) 443–6593.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986, Title III of Public Law 99–660 (42 U.S.C. 300 aa–10 *et seq.*) established the National Vaccine Injury Compensation Program (VICP) for persons found to be injured by vaccines. Under this federal program, petitions for compensation are filed with the United States Court of Federal Claims (Court). The Court, acting through special masters, makes findings as to eligibility for, and amount of, compensation. In order to gain entitlement to compensation under the VICP for a covered vaccine, a petitioner must establish a vaccine-related injury or death, either by proving that the first symptom of an injury/condition, as defined by the Qualifications and Aids to Interpretation, occurred within the time period listed on the Vaccine Injury Table (Table), and, therefore, is presumed to be caused by a vaccine (unless another cause is found), or by proof of vaccine causation, if the injury/condition is not on the Table or did not occur within the time period specified on the Table.

The statute authorizing the VICP provides for the inclusion of additional vaccines in the VICP when they are recommended by the Centers for Disease Control and Prevention (CDC) for routine administration to children. *See* section 2114(e)(2) of the PHS Act, 42 U.S.C. 300aa–14(e)(2). Consistent with section 13632(a)(3) of Public Law 103–66, the regulations governing the VICP provide that such vaccines will be included in the Table as of the effective date of an excise tax to provide funds for the payment of compensation with respect to such vaccines. 42 CFR 100.3(c)(8). The statute authorizing the VICP also authorizes the Secretary to create and modify a list of injuries, disabilities, illnesses, conditions, and deaths (and their associated time frames) associated with each category of vaccines included on the Table. *See* sections 2114(c) and 2114(e)(2) of the PHS Act, 42 U.S.C. 300aa–14(c) and 300aa–14(e)(2). Finally, section 2114(c)(2) of the PHS Act, 42 U.S.C. 300aa–14(c)(2), provides that:

''[a]ny person (including the Advisory Commission on Childhood Vaccines) [the Commission] may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following—

(A) receipt of any recommendation of the Commission, or

(B) 180 days after the date of the referral to the Commission,

[w]hichever occurs first, the Secretary shall conduct a rulemaking proceeding on the matters proposed in the petition or publish in the **Federal Register** a statement of reasons for not conducting such proceeding.''

On April 9, 2014, a private citizen submitted an email inquiry to the Secretary of Health and Human Services (HHS) regarding the VICP. This email asked why the condition of diabetes mellitus (DM) is not a listed injury on the Vaccine Injury Table (Table) in association with the measles, mumps, and rubella (MMR) vaccination, explaining that it is identified by the manufacturer as a possible adverse result of the MMR vaccine. The email also asked whether the Secretary would consider amending the Table to add DM as an injury for MMR vaccines. As such, the email was considered to be a petition to the Secretary to propose regulations to amend the Table to add the injury of DM for the category of MMR vaccines. Accordingly, pursuant to the VICP statute, the petition was referred to the Commission on June 5, 2014. The Commission voted unanimously to recommend that the Secretary not proceed with rulemaking to amend the Table as requested in the petition.

DM is a chronic disease in which there is a high level of sugar in the blood. There are two types: Type 1 and Type 2. Type 1 Diabetes is one of the most common chronic diseases in childhood. It is caused by insulin deficiency following destruction of the insulin producing pancreatic beta cells, resulting in absolute insulin deficiency. Type 2 Diabetes is characterized by hyperglycemia and insulin resistance and relative impairment in insulin secretion. Through the years, there have been many studies evaluating the risk of Type 1 Diabetes after MMR vaccination. However, HRSA's search of published literature did not reveal any studies discussing a causal relationship between Type 2 Diabetes and the MMR vaccine. The Secretary notes that vaccine package inserts list adverse events reported to vaccine manufacturers during clinical trials even though they may not have been shown to have been caused by the vaccines.

In 2008, the Secretary contracted with the Institute of Medicine (IOM) to review the epidemiological, clinical, and biological evidence regarding adverse health events associated with specific vaccines covered by the VICP.[1] The IOM committee reviewed the relevant studies through 2011 and concluded that ''[t]he evidence favors rejection of a causal relationship between MMR vaccine and Type 1 Diabetes.'' Specifically, the epidemiologic studies consistently reported a null association, or no association between the MMR vaccine and Type 1 Diabetes. The IOM committee concluded that the mechanistic evidence regarding an association between MMR vaccine and Type 1 Diabetes was lacking.

In 2012, the Cochrane Collaboration reviewed and assessed studies in the Cochrane Central Register of Controlled Trials.[2] The specific conclusion was that MMR vaccine was unlikely associated with Type 1 Diabetes. A recent study by Duderstadt et al. (2012)[3] was not reviewed by the IOM Committee and the Cochrane Collaboration. This was a retrospective cohort study among U.S. military personnel, which evaluated whether vaccination increased the risk of Type 1 Diabetes. The result was that there was no increased risk of diagnosed Type 1 Diabetes after administration of any studied vaccines, including the MMR vaccine. Current scientific literature consistently shows that there is no causal association between MMR vaccination and Type 1 Diabetes. As noted above, the VICP's search of published literature did not reveal any studies discussing a causal relationship between Type 2 Diabetes and the MMR vaccine.

In light of the literature discussed above, I have determined that there is no reliable scientific evidence of a causal association between MMR vaccine and DM. Therefore, I will not amend the Table to add DM as an injury associated with the MMR vaccine.

Dated: April 23, 2015.

Sylvia M. Burwell,

Secretary.

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[1] IOM, Adverse Effects of Vaccines: Evidence and Causality (Washington, DC: The National Academies Press, 2012):204–211.

[2] Demicheli, V., A. Rivetti, et al. ''Vaccines for Measles, Mumps and Rubella in Children.'' Cochrane Database System Rev 2: CD004407 (2012): 19.

[3] Duderstadt, S., C. Rose Jr., T. Real, J. Sabatier, B. Stewart, G. Ma, U. Yerubandi, A. Eick, J. Tokars, M. McNeil. ''Vaccination and Risk of Type 1 Diabetes Mellitus in Active Component U.S. Military, 2002–2008. Vaccine 30:813–819, (2012).